

Subject: Whistleblower letter  
From: Brad Racino <bradracino@inewssource.org>  
Date: 8/12/19, 12:58 PM  
To: emah@ucsd.edu  
CC: Jill Castellano <jillcastellano@inewssource.org>

Good afternoon Mr. Mah,

This morning we received a whistleblower complaint alleging a number of problems within UCSD's HRPP (attached).

The letter specifically referred to actions taken by you in regards to your leadership position within UCSD.

Please find the following list of questions and let me know when would be a good time to talk about them:

1. How do you plan to address the concerns raised in this letter? Will you conduct an investigation into the claims? Will you report these allegations to any outside agencies?
2. The letter says that unlike other HRPP offices in the UC system that are housed under the Vice Chancellor for Research Compliance, the UCSD HRPP is overseen by the ACTRI Director. Do you believe HRPP would better perform its mission if it didn't fall under ACTRI? Have any efforts been made to move the office out from under ACTRI?
3. How does ACTRI monitor HRPP and ensure its employees are following its mission and making decisions to protect research subjects?
4. The letter says that IRB committees have been pressured to approve studies that do not meet the criteria for approval, adding that senior leadership at HRPP "purposefully neglects" or "perpetuates" noncompliance. Are these statements accurate? Can you ensure that research studies performed at UCSD meet all government regulations and UCSD policies before approving them?
5. Does the HRPP have anything like the Quality Improvement Unit (QIU) at UCSF or UCLA to review staffing levels and conduct post-approval monitoring, education/training and other quality improvement activities? If not, would UCSD consider establishing a unit like this to ensure its IRBs are following their mission and protecting research subjects?
6. The letter states that Karen Allen supervises IRB staff as well as research staff. It says she remains in IRB committee meetings when IRB protocols submitted by her own research coordinators are voted on. It also claims she edits and approves IRB letters for studies submitted by her coordinators. Is this accurate? If so, wouldn't that be a conflict of interest that could damage the integrity of the research projects?

Thank you.

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P.S. We want to hear from you! [Take a brief survey](#) to help us get to know you and the topics you want us to look into.

—Attachments:

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Noncompliance and Human Subject Research Violations Report at  
UCSD.pdf

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KB